AMENDMENTS TO THE CLAIMS

The following Listing of Claims replaces all prior versions, and listings, of claims in this application.

**Listing of Claims:**

1. (Currently Amended) A process for producing a storage stable virus composition, the process comprising:

(a) freezing a virus composition comprising a respiratory syncytial virus (RSV), a parainfluenza virus (PIV), ~~mumps virus, measles virus, metapneumovirus~~ or a combination thereof below its glass transition temperature in a time of 60 minutes or less at a rate of -0.5°C to -2.5°C per minute; and

(b) lyophilizing the virus, wherein the lyophilized virus composition has less than about a 17.6% log PFU loss after at least one year at a storage temperature of about 1°C to about 10°C as compared to the lyophilized virus composition before storage.

2. (Canceled)

3. (Previously presented) The process of claim 1, wherein the glass transition temperature is about -30°C to about -50°C.

4. (Canceled)

5. (Original) The process of claim 3, wherein the glass transition temperature of about -35°C is reached in a time of 20 minutes or less.

6. (Previously presented) The process of claim 1, wherein the virus composition is formulated in a 5.0 mM to about 20 mM phosphate buffer solution comprising sodium and/or potassium monobasic and dibasic salts and having a pH of about 6.5 to about 7.8.

7. (Canceled)

8. (Previously presented) The process of claim 6, further comprising about 0.25 mM to about 25 mM HEPES, about 0.01 mM to about 1 mM magnesium chloride, and about 0.01 mM to about 1 mM calcium chloride.

9-10. (Canceled)

11. (Previously presented) The process of claim 8, further comprising sucrose, L (+)-glutamic acid or L (+)-glutamic acid monosodium salt or a mixture of L (+)-glutamic acid/L (+)-glutamic acid monosodium salt, and human albumin (HA).

12. (Canceled)

13. (Original) The process of claim 11, further comprising soy peptone.

14-17. (Canceled)

18. (Original) The process of claim 1, wherein the virus composition has less than about a 1.0 log PFU loss after one year of storage at about 1°C to about 10°C.

19-21. (Canceled)

22. (Original) The process of claim 1, wherein lyophilizing the virus composition is further defined as:

(a) placing about 0.5 mL to 0.6 mL of the virus composition in a vial and cooling to a temperature of about 5°C;

(b) placing the vial on a lyophilization shelf and decreasing the shelf temperature from 5°C to -50°C at a rate of about -1.0°C per minute to about -2.0°C per minute;

(c) holding the shelf temperature at about -50°C for 60 minutes;

(d) reducing chamber pressure to 0.10 Torr and holding the shelf temperature at about -50°C for 30-60 minutes;

(e) increasing the shelf temperature from -50°C to 0°C at a rate of about 1.0°C per minute to about 2.0°C at about 0.10 Torr and holding the shelf temperature at about 0°C for about 540 minutes to about 720 minutes;

(f) increasing the shelf temperature from 0°C to 15°C at a rate of about 0.5°C per minute at about 0.10 Torr and holding the shelf temperature at about 15°C for about 600 minutes to about 720 minutes, and

(g) filling the vial with nitrogen gas and hermetically sealing the vial.

23. (Previously presented) The process of claim 1, wherein lyophilizing the virus composition is further defined as:

(a) placing about 0.5 mL to 0.6 mL of the virus composition in a vial and cooling to a temperature of about 5°C;

(b) freezing a lyophilization shelf to a temperature of about -70°C;

(c) placing the vial on the lyophilization shelf and holding the temperature at about -70°C for about 60 minutes;

(d) reducing chamber pressure to 0.10 Torr and increasing the shelf temperature from -70°C to -50°C at a rate of about 1.0°C per minute;

(e) increasing the shelf temperature from -50°C to 0°C at a rate of about 1.0°C per minute to about 2.0°C per minute at about 0.10 Torr and holding the shelf temperature at about 0°C for about 540 minutes to about 720 minutes;

(f) increasing the shelf temperature from 0°C to 15°C at a rate of about 0.5°C per minute at about 0.10 Torr and holding the shelf temperature at about 15°C for about 600 minutes to about 720 minutes, and

(g) filling the vial with nitrogen gas and hermetically sealing the vial.

24. (Currently amended) A process for producing a lyophilization stable bulk volume virus composition, the process comprising:

(a) placing a liquid virus composition having a volume of at least 50 mL in a lyophilization tray, wherein the virus composition comprises respiratory syncytial virus (RSV), a parainfluenza virus (PIV), ~~mumps virus, measles virus, metapneumovirus~~ or a combination thereof;

(b) freezing the virus composition below its glass transition temperature for at least about 20 minutes in a liquid nitrogen bath; and

(c) lyophilizing the virus composition,

wherein the lyophilized virus composition has less than about a 0.5 log PFU loss relative to the virus composition before lyophilization.

25. (Previously presented) The process of claim 24, wherein the glass transition temperature is about -35°C to about -45°C.

26-29. (Canceled)

30. (Previously presented) The process of claim 24, wherein the virus composition is formulated in a 5.0 mM to about 20 mM phosphate buffer solution comprising sodium and/or potassium monobasic and dibasic salts and having a pH of about 6.5 to about 7.8.

31-32. (Canceled)

33. (Previously presented) The process of claim 30, further comprising about 2.5 mM to about 25 mM HEPES, about 0.1 mM to about 1 mM magnesium chloride, and about 0.1 mM to about 1 mM calcium chloride.

34. (Canceled)

35. (Previously presented) The process of claim 33, further comprising sucrose, L (+)-glutamic acid or L (+)-glutamic acid monosodium salt and human albumin (HA).

36. (Canceled)

37. (Original) The process of claim 35, further comprising soy peptone.

38-40. (Canceled)

41. (Original) The process of claim 24, wherein lyophilizing the bulk volume virus composition is further defined as:

(a) placing the tray comprising the frozen virus composition at a temperature of about -50°C on a lyophilization shelf pre-cooled to a temperature of about -50°C and holding the temperature for about 60 minutes;

(b) reducing chamber pressure to 0.10 Torr and increasing the shelf temperature from -50°C to -23°C at a rate of about 0.23°C per minute at about 0.10 Torr;

(c) holding the shelf temperature at about -23°C for about 80 hours to about 100 hours;

(d) reducing chamber pressure to 0.02 Torr and increasing the shelf temperature from -23°C to 15°C at a rate of about 0.23°C per minute;

(e) holding the shelf temperature at about 15°C and at about 0.02 Torr for about 30 hours to about 40 hours;

(f) increasing the shelf temperature from 15°C to 25°C at a rate of about 0.17°C per minute at 0.02 Torr;

(g) holding the shelf temperature at about 25°C and at about 0.02 Torr for about 10 hours, and

(h) filling the chamber with nitrogen gas and hermetically sealing the tray under nitrogen gas in an aluminum pouch.

42. (Original) The process of claim 24, wherein lyophilizing the bulk volume virus composition is further defined as:

(a) placing the tray comprising the frozen virus composition at a temperature of about -70°C on a lyophilization shelf pre-cooled to a temperature of about -70°C and holding the temperature for about 60 minutes;

(b) reducing chamber pressure to 0.10 Torr and increasing the shelf temperature from -70°C to -23°C at a rate of about 0.23°C per minute;

(c) holding the shelf temperature at about -23°C at about 0.10 Torr for about 80 to 100 hours;

(d) reducing chamber pressure to 0.02 Torr and increasing the shelf temperature from -23°C to 15°C at a rate of about 0.23°C per minute;

(e) holding the temperature at about 15°C and 0.02 Torr for about 30 to 40 hours;

(f) increasing the shelf temperature from 15°C to 25°C at a rate of about 0.17°C per minute at 0.02 Torr;

(g) holding the temperature at about 25°C for about 10 hours, and

(h) filling the chamber with nitrogen gas and hermetically sealing the tray under nitrogen gas in an aluminum pouch.

43. (Withdrawn) A process for producing a storage stable liquid virus composition comprising respiratory syncytial virus (RSV), a parainfluenza virus (PIV), or a combination thereof, the process comprising:

(a) equilibrating a metal plate in a liquid nitrogen bath;

(b) placing a liquid virus composition in a nasal spray device;

(c) inserting the nasal spray device of step (b) into a metal holder;

(d) placing the metal holder on the equilibrated metal plate of step (a) for about ten minutes;

(e) removing the nasal spray device from the metal holder; and

(f) storing the nasal spray device at a temperature from about -20°C to about -70°C,

wherein the virus composition after steps (a) through (f) has less than about a 0.5 log PFU loss after 6 months storage.

44-45. (Canceled)

46. (Withdrawn) The process of claim 43, wherein the virus composition is at least 4.0 log PFU/0.2 mL after steps (a) through (f).

47. (Canceled)

48. (Withdrawn) The process of claim 43, wherein the virus composition is at least 4.0 log PFU/0.2 mL after a six month storage at a temperature of -70°C.

49. (Withdrawn) The process of claim 43, wherein the liquid virus composition is formulated in the absence of a protein stabilizer.

50. (Withdrawn) The process of claim 43, wherein the virus composition is formulated in a 5.0 mM to about 20 mM phosphate buffer solution comprising sodium and/or potassium monobasic and dibasic salts and having a pH of about 6.5 to about 7.8.

51-53. (Canceled)

54. (Withdrawn) The process of claim 43, further comprising about 0.25 mM to about 25 mM HEPES, about 0.01 mM to about 1 mM magnesium chloride, and about 0.01 mM to about 1 mM calcium chloride.

55. (Withdrawn) The process of claim 54, further comprising sucrose and L (+)-glutamic acid, L (+)-glutamic acid monosodium salt or a mixture of L (+)-glutamic acid and L (+)-glutamic acid monosodium salt.

56-59. (Canceled)

60. (Withdrawn) An immunogenic composition comprising the virus composition produced by the process of claim 1, dissolved in a pharmaceutically acceptable carrier.

61. (Withdrawn) An immunogenic composition comprising the virus composition produced by the process of claim 24, dissolved in a pharmaceutically acceptable carrier.

62. (Withdrawn) An immunogenic composition comprising the nasal spray virus composition produced by the process of claim 43.

63. (Withdrawn) A process for producing a storage stable virus composition comprising a virus selected from the group consisting of herpes simplex virus (HSV), cytomegalovirus (CMV), Epstein-Barr virus, Varicella-Zoster virus, influenza virus, poliovirus, rhinovirus, adenovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, Norwalk virus, togavirus, alphavirus, rubella virus, rabies virus, Marburg virus, Ebola

virus, papilloma virus, human papilloma virus (HPV), polyoma virus, coronavirus, vesicular stomatitis virus (VSV) and Venezuelan equine encephalitis virus (VEE), the process comprising:

(a) freezing the virus composition below its glass transition temperature in a time of 60 minutes or less; and

(b) lyophilizing the virus composition, wherein the lyophilized virus composition is stable for at least one year at a storage temperature of about 1°C to about 10°C.

64-85. (Canceled)

86. (Withdrawn) A process for producing a lyophilization stable bulk volume virus composition comprising a virus selected from the group consisting of HSV, CMV, Epstein-Barr virus, Varicella-Zoster virus, influenza virus, poliovirus, rhinovirus, adenovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, Norwalk virus, togavirus, alphavirus, rubella virus, rabies virus, Marburg virus, Ebola virus, papilloma virus, HPV, polyoma virus, coronavirus, VSV and VEE, the process comprising:

(a) placing a liquid virus composition having a volume of at least 50 mL in a lyophilization tray;

(b) freezing the virus composition below its glass transition temperature for at least about 20 minutes in a liquid nitrogen bath; and

(c) lyophilizing the virus composition,

wherein the lyophilized virus composition has less than about a 0.5 log PFU loss relative to the virus composition before lyophilization.

87-104. (Canceled)

105. (Withdrawn) A process for producing a storage stable liquid virus composition comprising a virus selected from the group consisting of HSV, CMV, Epstein-Barr virus, Varicella-Zoster virus, mumps virus, measles virus, influenza virus, poliovirus, rhinovirus, adenovirus, hepatitis A virus, hepatitis B virus, hepatitis C virus, Norwalk virus, togavirus, alphavirus, rubella virus, rabies virus, Marburg virus, Ebola virus, papilloma virus, HPV, polyoma virus, metapneumovirus, coronavirus, VSV and VEE, the process comprising:

(a) equilibrating a metal plate in a liquid nitrogen bath;

(b) placing a liquid virus composition in a nasal spray device;

(c) inserting the nasal spray device of step (b) into a metal holder;

(d) placing the metal holder on the equilibrated metal plate of step (a) for about ten minutes;

(e) removing the nasal spray device from the metal holder; and

(f) storing the nasal spray device at temperature from about -20°C to about -70°C,

wherein the virus composition after steps (a) through (f) has less than about a 0.5 log PFU loss after 6 months storage.

106-121. (Canceled)

122. (Withdrawn) An immunogenic composition comprising the virus composition produced by the process of claim 63, dissolved in a pharmaceutical acceptable carrier.

123. (Withdrawn) An immunogenic composition comprising the virus composition produced by the process of claim 86, dissolved in a pharmaceutically acceptable carrier.

124. (Withdrawn) An immunogenic composition comprising the nasal spray virus composition produced by the process of claim 105.